02-25-02

FORM PTO-1390 (REV. 5-93)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 1774/0K314

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

10/070072

INTERNATIONAL APPLICATION NO. PCT/EP00/08207	INTERNATIONAL FILING DATE August 21, 2000	PRIORITY DATE CLAIMED August 20, 1999

TITLE OF INVENTION

APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

APPLICANT(S) FOR DO/EO/US

Daniel LARSSON; Thomas LUNDEBERG

Applicant herewith submits to the United States Designated/Elected office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. [] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371 (f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S. C. 371 (b) and PCT Articles 22 and 39 (1).

4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. [X] A copy of the International Application as filed (35 U.S. C. 371 (c) (2))
   a. [] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau
   c. [] is not required, as the application was filed in the United States Receiving Office (RO/US)

6. [] A translation of the International Application into English (35 U.S. C. 371 (c)2)).

7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. [] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [] have been transmitted by the International Bureau.
   c. [] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.

8. [] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c) (3)).

9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (Unexecuted)

10. [] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. [] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. [] An assignment document for recording. A **separate** cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. [X] A FIRST preliminary amendment.
    [] A SECOND or SUBSEQUENT preliminary amendment.

14. [] A substitute specification.

15. [] A change of power of attorney an/or address letter.

16. [X] Other items or information:
    Copy of International Preliminary Examination Report, including claims 1-50 as amended during the International Phase pursuant to the telephone communication dated November 5, 2001, under PCT Article 34.

EXPRESS MAIL CERTIFICATE

Date 2/20/02 Label No. EV039137870US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

D B Peck

Name (Print)

Signature

JC19 Rec'd PCT/PTO 20 FEB 2002

U.S. APPLICATION NO. (if known see 37 C.F.R.1.50) 10/070072	INTERNATIONAL APPLICATION NO.: PCT/EP00/08207	Attorney's Docket Number 1744/0K314

17. [x] The following fees are submitted:		CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492 (a)(1)-(5)): Search Report has been prepared by the EPO [X] or JPO []	$890.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482)	$710.00		
No international preliminary examination fee paid to USPTO(37 CFR 4.482) but international search fee paid to USPTO (37 CFR 1.445 (a) (2)...	$740.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....	$1,040.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)....	$100.00		
=	**ENTER APPROPRIATE BASIC FEE AMOUNT =**	$890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than []20 []30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	**50-20**	30	X $18.00	**$540.00**	
Independent Claims	**2-3**		X $80.00	$00	
Multiple dependent claims(s) (if applicable)		+280		$280.00	
			TOTAL OF ABOVE CALCULATIONS =	**$1,430.00**	
Reduction by 1/2 for filing by small entity, if applicable.				**$0.00**	
			SUBTOTAL =	**$1,430.00**	
Processing fee of **$130.00** for furnishing the English translation later the [] 20 [] 39 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$	
			TOTAL NATIONAL FEE =	**$1,430.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). the assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property			+	$0.00	
			TOTAL FEES ENCLOSED =	**$1,430.00**	
				Amount to be refunded	$
				charged	$

a. [X] A check in the amount of $**1,430.00** to cover the above fees is enclosed.

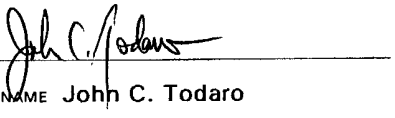
b. [] Please charge my Deposit Account No.04-0100 in the amount of $ to cover the above fees.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0100. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

John C. Todaro
Darby & Darby P.C.
805 Third Avenue
New York, New York 10022-7513

SIGNATURE 

NAME John C. Todaro

REGISTRATION NO. 36,036

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EXPRESS MAIL CERTIFICATE

Date 2/20/02 Label No. EV 039137870US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

D B Peck

Name (Print) Signature

PLEASE CHARGE ANY DEFICIENCY OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Customer No.: 07278

PATENT TRADEMARK OFFICE

Docket No: 1774/0K314

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Daniel LARSSON; Thomas LUNDEBERG

Serial No: TO BE ASSIGNED (National Phase of International Patent Application Serial No. PCT/EP00/08207, filed August 21, 2000)

Filed: CONCURRENTLY

For: APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

PRELIMINARY AMENDMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

Prior to examination, please amend the above-identified application as follows:

In the Specification:

Please insert the following immediately following the first paragraph on page 2 of the specification:

-- The prior art document US Patent No. 5,191,896 to Gafni et al. discloses an apparatus for measuring threshold sensitivity to a stimulus.

A further prior art document WO 97/06730 discloses an apparatus for determining constant alternating current perception threshold.--

In the Claims:

Please cancel claims 24-26 without prejudice or disclaimer.

Pursuant to 37 C.F.R. §1.121, please amend claims 1, 3, 11, 14, 15, 23, 27, 37 and 44, (as amended during the International phase pursuant to the telephone communication of November 5, 2001, under PCT Article 34) as follows (see the accompanying "marked up" version pursuant to §1.121):

1. (Amended) A sensation level measuring device for assessing the level of a sensation experienced by a person, comprising:

a stimulator devised to deliver a physical stimulus to said person;

an indication mechanism being actuateable by said person to indicate a level of said physical stimulus;

a registration mechanism for registering said indicated level;

means for delivering said physical stimulus as a pulsating stimulus having a predetermined frequency, and;

means for varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating stimulus.

3. (Amended) The measuring device as recited in claim 1, wherein said stimulator is further devised to vary the amplitude of said pulsating physical stimulus for the purpose of comparing said physical stimulus with a sensory component of said sensation.

11. (Amended) The measuring device as recited in claim 5, wherein said stimulator is capable of delivering said electrical energy in the shape of a voltage or a current in a square wave or a triangular wave.

14. (Amended) The measuring device as recited in claim 1, wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

15. (Amended) The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

23. (Amended) The measuring device as recited in claim 1, wherein:

said stimulator comprises a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person;

said indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;

said level registration means (114, 116) for registering a sensation level value corresponding to said sensation, and;

said means (122) for varying the pulse width of the physical stimulus with a constant predetermined frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

27. (Amended) A method of measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:

delivering a pulsating physical stimulus having a predetermined frequency to said person;

varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating frequency;

receiving, at a level of physical stimulus, an indication from said person, and;

registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

37. (Amended) The method as recited in claim 32, further comprising the step of delivering an electrical energy in the shape of a voltage or a current in a square wave or a triangular wave.

44. (Amended) The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

Remarks:

After entry of this amendment, claims 1-23 and claims 27-50 are pending.

The specification has been amended to cite two prior art references.

The claims were amended during the International phase pursuant to the telephone communication of November 5, 2001, under PCT Article 34 (attached, as Amended Sheets with the International Preliminary Examination Report of December 5, 2001). Claims 1, 3, 11, 14, 15, 23, 27, 37 and 44 are amended herein. Claims 24-26 are cancelled.

Support for amendments to claims 1 and 27 may be found in the specification as originally filed (published as WO 01/13793) at page 7, lines 10-33. Additional support for amendments to claim 27 may be found in the specification as originally filed at page 12, lines 31-39 and page 13, lines 1-8.

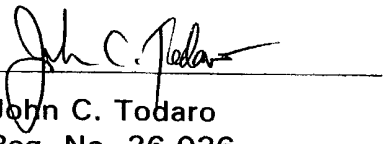
Claims 3, 11, 14, 15, 23, 37 and 44 are amended to change their format from improper multiple dependent claims to proper multiple dependent claims, and to further place them in better condition for prosecution.

No new matter has been added as a result of this amendment.

In view of the above amendments and remarks, examination on the merits is respectfully requested.

Respectfully submitted,

February 20, 2002



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PATENT TRADEMARK OFFICE

Docket No: 1774/0K314

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Daniel LARSSON; Thomas LUNDEBERG

Serial No: TO BE ASSIGNED (National Phase of International Patent Application Serial No. PCT/EP00/08207, filed August 21, 2000)

Filed: CONCURRENTLY

For: APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

PRELIMINARY AMENDMENT (MARKED UP COPY)

In the Claims:

1. (Amended) A sensation level measuring device [comprising a stimulator devised to deliver a physical stimulus, characterized in] for assessing the level of a sensation experienced by a person, comprising:

a stimulator devised to deliver a physical stimulus to said person;

an indication mechanism being actuateable by said person to indicate a level of said physical stimulus;

a registration mechanism for registering said indicated level;

means for delivering said physical stimulus as a pulsating stimulus having a predetermined frequency, and;

means for varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating stimulus

[for the purpose of comparing said physical stimulus with an affective component of said sensation].

3. (Amended) The measuring device as recited in [claim 1 or 2] claim 1, wherein said stimulator is further devised to vary the amplitude of said pulsating physical stimulus for the purpose of comparing said physical stimulus with a sensory component of said sensation.

11. (Amended) The measuring device as recited in claim 5, wherein said stimulator is capable of delivering said electrical energy in the shape of a voltage or a current in a square wave [and/or] or a triangular wave[, preferably having a frequency in the range of 1-100 Hz].

14. (Amended) The measuring device as recited in [claim 1, 2, 3 or 4] claim 1, wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

15. (Amended) The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave [and/or] or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

23. (Amended) The measuring device as recited in [claim 1, 2, 3 or 4] claim 1, wherein:

said stimulator comprises a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person; [and the measuring device further comprising]

[an] said indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;

[a] said level registration means (114, 116) for registering a sensation level value corresponding to said sensation, and;

said means (122) for varying the pulse width of the physical stimulus with a constant predetermined frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

27. (Amended) A method of measuring the level of a sensation, perception or integrated skill of a person, [characterized in] comprising the steps of:

delivering [to said person a pulse width modulated] a pulsating physical stimulus [for comparing with an affective component of said sensation] having a predetermined frequency to said person;

varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating frequency;

receiving, at a level of physical stimulus, an indication from said person, and;

registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

37. (Amended) The method as recited in claim 32, further comprising the step of delivering [a] an electrical energy in the shape of a voltage or a current in a square wave [and/or] or a triangular wave[, preferably having a frequency in the range of 1-100 Hz].

44. (Amended) The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of

a temperature variation in a square wave [and/or] or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

Technical Field

The present invention relates generally to an apparatus for assessing the level of comfort or discomfort in a positive or negative sensation experienced by a person. More particularly, the invention relates to an electronic apparatus being devised to provide a variable stimulus to the person until the applied stimulus matches the experienced sensation.

Background

In medical as well as psychological treatment there is a need to quantify the sensation experienced by the patient, for example in order to select an appropriate treatment and to determine the need of drugs or the effect of a pursued treatment. This is based in the individual need for an adequate treatment as well as for conveying an understanding of the personal situation for example to a doctor. There is also a social need to control the overall consumption of drugs and the general well-being of the population. In order to meet these and other needs, an efficient tool for quantifying sensations, particularly those related to medical or psychological disorders, is required.

The best known field for quantifying sensations is perhaps the assessment of pain, and prior art within this field has evolved from general statements of the status in response to questions from a doctor to simple aids such as the widely used sliding scale for quantifying a sensation of pain. Commonly used such scales are for example the visual analogue scale (VAS) and other ordered category scales, i.e. numeric rating scales (NRS). A disadvantage with these methods is the unreliability inter alia due to a relative scale which is strongly dependent on unconscious or conscious subjective influence by the patient. Other limitations in the scale based methods are the fixed end points of the scale entailing a limited range of measurement and the fact that comparisons can only be made between different measurements on the same individual, not between different individuals.

In order to produce a more reliable result an electronic instrument and a method for measuring an arbitrary feeling e.g. pain or nausea has been suggested and presented in the patent publication WO 97/24068 (Laserow), which is herewith incorporated by reference. This instrument is devised to apply a physical stimulus to the patient, e.g. in the form of an electrical current, and the stimulus is increased until the patient experiences a discomfort that is comparable to the pain or nausea that is to be quantified. The patient then actively or passively ceases the induced stimulus and a value is registered. It has been found that this way of quantifying pain or other discomfort is repeatable and more reliable than previous methods. Furthermore, the measurement is unbiased since the patient is not aware of the resulting value but only of the stimulus to be compared to the feeling to be assessed.

Another prior art method directed to the quantification of the emotional state following a dysphoric condition, such as depression, anxiety or pain; is disclosed in US Patent No. 4,844,091 to Bellak. This piece of prior art describes a method wherein an increasing acoustical stimulation is applied to a patient until the level of the acoustical stimulation is associated with the level of the dysphoric condition.

It is well known that many sensations have a sensory component as well as an affective component. The sensory component typically corresponds to the intensity of the sensation, where it is located, duration and so on, whereas the affective component rather corresponds to the discomfort and the aspects that affect the quality of life. This is probably due to the fact that a sensation, e.g. pain, is on one hand registered in the cerebral cortex which is responsible for the experience of intensity, localisation and duration. On the other hand the sensation is also registered in nuclei that affect the emotional life, i.e. in the limbic system. This fact entails difficulties in determining the appropriate measures to be taken against for example a dysphoric condition. So may, for example, a much lesser amount of analgesics actually be needed in order to eliminate pain than the measurement value according to prior art method suggests. In other situations, e.g. where a mainly emotional sensation should be assessed there is in prior art an uncertainty as to what component is actually measured.

Accordingly, there is a need for an improved apparatus that gives a reliable and repeatable indication of the different components of the experienced sensation.

From a practical point of view the evaluation of symptoms and different functional disorders of patients is a frequently occurring task in the normal clinical work. The evaluations are registered in order for the purpose of establishing optimal opinions of the state of health, of deciding on a treatment or to follow up the result of a treatment. Furthermore, the clinical evaluation methods have to be fast and simple to perform in order to fit into the stressful working conditions of today. The instruments that are used in the evaluation should also be tested to give reliable results, i.e. to give the same results in repeated measurements and to measure the intended parameters. Naturally, the instruments also must be safe to use without any risk of hurting the patient.

Accordingly, there is furthermore a need for an improved apparatus that ensures a reliable assessment of the sensations to be measured also under disturbing circumstances and despite possible attempts from the patient to manipulate the measurement.

Objects of the Invention

It is therefore an object of the present invention to solve the problem of providing an improved apparatus that enables separate measuring of the affective component of a sensation.

An aspect of the problem to be solved is to distinguish between the sensory and the affective components of sensations. More particularly, this aspect of the problem concerns

how to measure the sensory and the affective components, respectively.

Another aspect of the problem is to provide a suitable type of stimulation.

Yet another aspect of the problem to be solved is to ensure the reliability of a measurement and to render the detection of an erroneous measurement possible.

Summary of the Invention

The present invention is based on the realisation of the inventors that the result of the measurement is dependent on the type of the applied stimulus. The basic principle of the invention is to let a person compare an induced physical stimulus with a current or a previously experienced sensation, perception or integrated skill by making an analogy between the sensation caused by the induced stimulus and the sensation to be measured. This is also known as sensation matching, e.g. pain matching.

The inventors have found that sensations to be measured are best compared with a pulsating stimulus in order to achieve a reliable result. In parts of a measurement or for measuring specific sensations or components of sensations, a constant stimulus, which can be regarded as a pulsating stimulus having an infinite pulse width, may be used. Stimuli according to different embodiments of this invention are for example energy forms such as electricity, cold and heat. Electrical stimulation is perhaps the most reliable energy form for the stimulus since it is easy to control and it gives constant measurement values, which in its turn generates measurement results that are comparable between different individuals. However, other energy forms may be more suitable in specific conditions or situations.

The sensory component of a sensation has been found to be best compared with a stimulus in the shape of a pulsating energy wave where the amplitude is varied, in most cases increased, in order to determine a level of this component. The sensory component typically reflects the intensity or strength of a compound sensation having both components.

Furthermore, it has been found that specific stimuli are comparable with affective components of sensations and are according to the invention applied in order to discriminate the affective component from the sensory component of the sensation. In accordance with an embodiment of the invention, the affective component of a sensation is advantageously compared with a stimulus in the shape of a pulsating energy wave where the pulse width is varied, in most cases increased, in order to determine the relevant level of the affective component. A particularly advantageous embodiment of such a pulse width modulated pulsating stimulus is applied with a constant amplitude and a constant frequency. In a series of measurements the pulse width modulation may be employed with different levels of amplitudes and frequencies that are fixed within each measurement. The affective component typically reflects the level of comfort or discomfort in a compound sensation having both components. When measuring a sensation known to have none or

only a negligible amount of one of the components, it may be sufficient to apply the stimulus suitable for the mainly occurring component. However, it is often an advantage to cross match the measurement results for different components.

Physiological reasons for the suitability of the mentioned stimulus variation schemes for the affective component and the sensory component, respectively, are explained below. In addition, experimental test series on human test groups strongly support this functional relationship.

Different sensations may, according to an embodiment of the invention, also be measured by applying different frequencies for different sensations. There are physiological as well as a psychological reasons for this, i.e. physical stimuli having certain varying properties or parameters, e.g. in terms of amplitude, pulse width, frequency settings or increase rate, are suitable for comparing certain sensations. When conducting measurements on different types of sensations it is also psychologically appropriate to vary the type of stimulation in order to separate the sensations in the mind of the measured person. In one embodiment of the invention, the apparatus is devised to selectively, in a predetermined or random scheme, alternately deliver a first physical stimulus that is comparable with an affective component of the sensation and a second physical stimulus that is comparable with a sensory component of the sensation. The parameter values are registered and assorted according to the measured component , and then presented to the user for evaluation.

According to an aspect of the invention, the reliability of a measurement is checked by conducting a series of measurements with different variations in the stimulation. In a preferred embodiment of the invention this variation is achieved by varying the increase rate of the physical stimulus, e.g. varying the increase rate of the pulse width or the pulse amplitude. So, if for example a test object indicates a sensation match after the same period of time in two different stimulation sequences of the same measurement session, different measurement results in terms of parameter values will be obtained. Thereby it is possible to detect erroneous measurement conditions or an unconscious or conscious attempt to manipulate the measurement. If on the other hand the test object indicates a match at the same or in a close range of parameter values in subsequent stimulation sequences with different increase rates, it is a strong indication that the measurement is correct and reliable. In a basic variety of this inventive feature, the apparatus is devised to deliver the physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement. Further features are of this embodiment are explained below.

The reliability of the measurement is in another embodiment of the invention checked by first detecting and storing the perception threshold of the person, by gradually increasing the stimulation until the person signals a perceived stimulation In a similar manner the sensation threshold of the person is detected, i.e the threshold at which the

patient begins to experience a similar or an analogue sensation. This threshold is perhaps mostly used in connection with pain measurement where it is consequently called pain threshold, i.e. the point at which the patient begins to experience pain. Again in a similar manner, the tolerance threshold of the person is detected and stored when the person signals an unbearable stimulation. The inventors have found that the most relevant measurement results are obtained in the range between the perception threshold and the tolerance threshold, evidently because below and above these threshold the patient is generally not able to distinguish between different stimulation levels. In a subsequent measurement session the scales of the measurement values may then be adjusted dependent on the stored individual threshold values. For checking purposes, it is utilised in embodiments the invention the fact that it is unlikely that someone would estimate a sensation as corresponding to a stimulus below the perception threshold. In ordinary measuring, valuable measuring time is saved by starting the stimulation close to the perception threshold. Furthermore, it is preferable to adjust the scale running from absence of sensation to unbearable sensation such that it starts on the perception threshold. For safety reasons it is also preferable to set a maximum stimulus below the tolerance threshold in order to minimise the risk of hurting the patient.

Experimental studies on patients with chronic nociceptive or neurogenic pain have shown that the apparatus according to the invention presents a less systematic disagreement and a greater augmented rank order coefficient than the above mentioned VAS and NRS. Advantages that are obvious from the studies are that the inventive apparatus is simple and safe to use, and that it seems to give more objective values for further analyses. Furthermore, neither any possible expectation of the test leader nor of the patient influences the direct outcome of the measurements.

Brief Description of the Drawings

The invention will now be further described in conjunction with the drawings, wherein Fig 1 and Fig 2 show block diagrams of the functional components of the inventive apparatus.

Detailed Description of Embodiments

The invention facilitates the measurement of a senso-neuropsychological quantity in a person by inducing sensation levels, e g energy levels or pain levels, as a reference The person in his or her turn is instructed to compare the induced level with the level to be measured, which for example can be a level of an actual pain, a remembered pain or a level of another sensation, perception or integrated skill relating to sensory modalities such as sight, smell, hearing, touch or taste. The level to be measured can also be a level of a feeling or of an ability. The person is further instructed to indicate which induced sensation level that best coincides with the level of the senso-neuropsychological quantity that is

measured. In compound sensations both the sensory as well as the affective component can be measured by means of the invention. When it comes to abilities, diability or an integrated skill which requires an observer of the patient to assess the level, the stimulus is subjected to the observer who matches the induced stimulus with his or hers perception of the level of the patient's senso-neuropsychological quantity.

The term senso-neuropsychological quantity is in this text used as a common expression for the complex of sensations, perceptions and integrated skills and disabilities. However, for the sake of simplicity also the simpler term sensation will be used as a synonym. Such quantities or sensations for example include pain, nausea, tinnitus, tiredness, muscle weakness, spasticity, vomiting need, anxiety, fear, state of being, abstinence, itch, luxation, heartbeat, cramp, suffocation, allergy, sleep, sensitivity, motoric phenomena or motoric problems, ache, apathy, ataxia, aphasia, athetosis, degree of infection, fever, numbness, swelling, intoxication, inflammation, burning, cognitive or mnemonic ability, joy, comfort, vision, paresthesia, dysphagia, sweating reflexes, movement, quality of life and ADL (active daily living skills).

In a first embodiment of the invention the physical stimulation is achieved by delivering an electrical energy wave, preferably electrical pulses to the nerves in the skin of a person. Nerve fibres in a resting state have a potential difference of 70mV across the fibre membrane, the inside being negative and the outside positive. When a nerve is stimulated an action potential arises from sequential changes in the selective permeability of the membrane to sodium (Na+) and potassium (K+) ions through channels. These voltage-gated ion channels are critical for generating action potentials. The nervous system expresses a rich variety of types of voltage-gated ion channels and each type has itself many variants. The channels differ in their kinetics of activation, voltage activation range and sensitivity. Also the opening and closing of certain voltage-gated ion channels can be modulated by various cytoplamic factors, resulting in increased flexibility of the neuron's excitability properties. In general the amplitude of current needed to stimulate a nerve is inversely proportional to its diameter. Thus the small C-fibres carrying the dull and aching pain associated with unpleasantness need the highest current or voltage amplitude and the longest pulse width whereas the small A-delta fibres carrying the sharp and intense pain requires a shorter pulse width to be stimulated. Furthermore, the impedance of the skin is dependent on pulse width, the impedance being much less for shorter pulses.

In the present invention, the inventors have utilized these basic physiological differences and constructed a sensation matching unit enabling assessment of sensation intensity, e.g. pain intensity, with an amplitude modulated stimulation signal using short pulses with fixed pulse width and increasing pulse amplitude thereby stimulating mainly A-delta fibres. This stimulation mode is in the invention used to measure the sensory component of sensations.

Furthermore, the affective component of a sensation such as discomfort associated with pain or unpleasantness is in accordance with the invention measured with a pulse width modulated stimulation signal using fixed pulse amplitude and an increasing pulse width thereby stimulating mainly C-fibres.

The invention is mainly intended to be applied in a portable measurement device such as the one disclosed in the above mentioned prior art document WO 97/24068 (Laserow), however other stationary or semi-stationary apparatuses are also conceivable within the inventive concept.

Fig 1 shows a block diagram of the functional structure of embodiments of the invention. The functional structure comprises a stimulus signal generator 102 coupled via means 106 for providing a pulsating stimulus to stimulus induction means 104, which in use are intended to be applied to the skin of a person for inducing a stimulus. A control unit 114, for example a control processor, is coupled to the stimulus signal generator 102 via an amplitude variation means 120 devised for varying the amplitude of the pulsating stimulus signal and thereby also varying the output stimulus in order to measure the level of a sensory component of a sensation. The control unit is also coupled to the pulsating stimulus providing means 106 via a pulse width variation means 122 devised for varying the pulse width of the pulsating stimulus signal in order to measure the level of an affective component of a sensation. The control unit is further coupled to a memory 116 for storing registered measurement values and control instructions for predetermined control schemes, and a display 118 for the visual presentation of an obtained measurement value or other information. The control unit is also optionally coupled to a control switch 124, e.g. a button, for starting, stopping or halting a measurement sequence at for example a perception threshold, sensation threshold, tolerance threshold or sensation level. In a preferred embodiment, the apparatus is devised to stop a variation of the pulsating properties of the stimulus in response to an actuation of the control switch 124, and the apparatus is devised to keep the pulsating property at its current level. So, for example, may the patient stop an increase in amplitude or pulse width at a level which seems to match the measured sensation and consider whether the level is correct. If the patient indeed considers the level to be correct, the patient releases his or her contact with the induction means 104. This leaves an open circuit which is detected by the apparatus, whereupon it is devised to automatically store the current value of amplitude and/or pulse width. A separate electrical circuit may be provided for the detection of an open circuit due to the patient's release of the contact with the induction means. If the halted level is not considered to be corrected, the patient may continue the increase, or variation, by releasing the button, resuming the contact or switch back to an initial switch position.

In the embodiment as shown in Fig 1, the means 106 for providing a pulsating stimulus further comprises means 108 for providing a pulsed current stimulus intensity, e.g. in the shape of an oscillator, and/or means 110 for providing a square waved stimulus

intensity, e.g. in the shape of a square wave or a triangle wave generator, either of the means 108 and 110 being devised to provide a stimulus signal in the form of a pulsed current having a frequency in the range of 1-100 Hz. In Fig 1 is also shown a switching means, controllable by the control unit and being devised to switch between the different wave forms.

In Fig 2, a more specific embodiment devised for delivering stimuli in the shape of a pulsated electrical current is shown. One of two electrodes 204 is coupled to a switched power supply 216 which in its turn is coupled or couplable to an energy source 218, e.g. a battery. The second electrode 204 is coupled to a constant current generator (CCG) 202 for generating a stimulus signal. The switched power supply 216 and the constant current generator 202 are coupled to a microprocessor 206 provided with an in/out (I/O) interface 212 such as a key board and/or a display. The pulses are generated by means of the microprocessor and conveyed to the electrode 204 from the constant current generator 202 via a digital to analog converter (D/A) 210 coupled intermediate the microprocessor 206 and the constant current generator 202. In this embodiment the amplitude variation means, the pulse width variation means and means for achieving a selected pulse shape are realised by a specific program run on the microprocessor. Different curve forms and increase rates are in a similar manner also achieved by the microprocessor.

An analog to digital (A/D) converter 208 is further coupled between the constant current generator 202 and the microprocessor 206 in order to facilitate a feedback for detection of closed or open circuit between the electrodes. This detection is provided in order to control the start of a measurement sequence when the electrodes are gripped by a person and/or the registration of a measurement value when the electrodes are released by said person and the circuit is broken.

In a first embodiment devised for applying an electrical current stimulus, the stimulus signal generator comprises a constant current generator or a constant voltage capable of delivering an electrical current through a resistance preferably in the range of 0-20 kohm. The apparatus can be either current controlled or voltage controlled and the parameter scales adjusted in accordance with the realised control type. The electrodes of preferred embodiments of the apparatus are intended to be applied to the skin of the persons to be measured. The electrodes are thereby preferably devised to contact the skin between the fingers in a tweezers grip and are therefore provided with a metal surface or a conductive silicone rubber surface

This apparatus would further be capable to vary the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range of 0 5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds. The apparatus would also or instead further be capable to vary the pulse width of an electrical stimulus signal in the range of 0-1000 microsecond, preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having

a fixed amplitude in the range of 5-20 mA. In one embodiment or application of the invention the pulsating physical stimulus or the stimulus signal is pulse width modulated by varying the pulse width but maintaining for a predetermined period of time a fixed amplitude and/or a fixed frequency. It is clear that this feature cannot be achieved with a sinus wave, it is rather required an unsymmetrical pulse wave in the sense that pulse and base level can have a different duration.

In either forms of stimulus, amplitude modulated or pulse width modulated, the pulse wave may be biased or superposed on a constant current in order to overcome a basic skin resistance. The skin resistance may be different for different persons, for example due to different bodily constitution or personal skin properties. Preferably, adjustments in the stimulation scheme due to such personal properties are stored for example in a digital storage device or in the shape of parameter values that can be input into or adjusted on measurement devices in accordance with the invention. Thereby ensuring reliability and repeatability of measurements on a specific person.

In order to increase the reliability of the measurement apparatus as discussed above, one embodiment is devised to increase the pulse width of the electrical current stimulus signal at a first increase rate in a first pulse width range. This is, in a preferred embodiment employed such that the pulse width increases from 0-250 microseconds within a first time period between 15 and 40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds within a second time period between 15 and 40 seconds, e.g. in 20 seconds. The apparatus is further devised to increase the amplitude of an electrical current stimulus signal at a first increase rate within a first amplitude range and at a second increase rate within a second amplitude range. The first and second amplitude ranges are different selections of combinations of amplitude ranges from the range of 0-100 mA and time periods between 5 and 80 seconds. For example, the increase rate may be such that the amplitude increases from 0-100 mA within a certain time period, which time period may last between 5 and 80 seconds

The purpose of using different time periods for the increase of pulse width or amplitude within a specific range, and thus the increase rate, is to make the measurement independent of the subjected person's perception of time. With varying increase rates from one test to another, the person subjected to the test is not led to make his or her indication based on the memory of the previous test, regarding the time elapsed since the beginning of the stimulus induction The person therefore needs to focus only on the induced stimulus, which in turn results in a more reliable measurement. For this reason, embodiments of the inventive apparatus is devised to never use the same time period, for a certain increase range and a certain person, twice in a row The stimulator may for example be devised to repeatedly in predetermined time intervals randomly select a new increase rate. For example, the apparatus may be devised to change said time period randomly, although with a time period of at least 5 seconds, between every two tests

In order to adjust the scales of the measurement result, one embodiment of the invention is devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold. This perception threshold is preferably found in a dedicated measurement cycle. Likewise is another embodiment devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.

In addition to the operation with increasing current and/or heat amplitude, as well as increasing pulse width, the inventive apparatus is capable of running according to a randomized stimulation scheme. In such a scheme, the induced stimuli has a random value both with regard to amplitude and, for electrical current, pulse width. Preferably, higher values close to the tolerance threshold are avoided in the randomized stimulation scheme. A certain random value, or set of values, is maintained for a specific time period, long enough for a person to be able to indicate that the stimuli matches the sensation to be measured. After said time period, the induced stimuli assumes a new random value, or set of values. Thus, in varieties of the invention, the stimulator is devised to deliver a physical stimulus with a randomly selected amplitude within a predetermined amplitude range, and to repeatedly in predetermined time intervals randomly select a new amplitude. Still a further variety is devised to deliver a physical stimulus with a randomly selected pulse width within a predetermined pulse width range, and to repeatedly in predetermined time intervals randomly select a new pulse width.

In one variety of the inventive apparatus the stimulus induction means 104 comprises a heat generating devise for emitting a stimulus by exchanging or inducing thermal energy with the skin of the person. The thermal energy exchange may be carried out by delivering heat to the skin of the person or by cooling the skin of the person. Different examples of such heat generating devices are resistive coils, peltier elements and lasers, such as argon lasers or carbon dioxide lasers. In the latter examples, radiation energy is transformed to heat in the skin. When using heat as stimulus, the apparatus would be devised to provide a heat stimulus having an amplitude increasing in a range of 20-60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades. The increase rate would typically be varied such that the heat stimulus increases from a start temperature to a maximum temperature during an interval in the range of 10-60 seconds.

In one embodiment, the stimulator is devised to be capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature. In another embodiment, the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature. The stimulator is typically capable of

delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds. The thermal energy exchange stimulator may also be designed to deliver an increasing, continuous , i.e. not pulsating, thermal energy stimulation. Dependent on the thermal inertia of the selected stimulation induction means, the pulsating properties of a pulsating stimulation may be more or less accentuated.

Specific embodiments are designed such that the physical stimulus is achieved by means of delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades. The stimulator may furthermore be devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

In embodiments based on cooling, the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades. Typically, the stimulator would then be devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

The internal structure of an apparatus for stimulation with thermal exchange is basically the same as the one for electrical stimulation, since the thermal elements or electrodes, whatever heating or cooling method is employed, will preferably be electronically controlled in the same manner as the electrical stimulator.

The physiological basis for measuring by means of thermal exchange stimulation in accordance with the invention is that humans recognize four distinct types of thermal sensations, namely cold, cool, which may be painful, warm and hot, which also may be painful. These thermal sensations result from differences between the external temperature of the air or of objects contacting the body and having the normal skin temperature of about 34C. Thermal receptors modulate their firing or activity as a function of temperature. At constant temperature they have tonic discharges, firing action potentials at a steady rate governed by the actual temperature sensed. Cold and warmth receptors fire action potentials continously at low rates when the skin temperature is set at its normal value of 34C. The steady firing rate does not increase or decrease monotonically if the skin is slowly warmed or cooled. Instead, each class of thermal receptors shows peak firing at a preferred skin temperature Cold receptors are most active at 25C whereas warmth receptors are most active at 45C. Temperatures below or above these values evoke progressively weaker responses Warmth receptors are unresponsive to hot temperatures, as stimuli above 50C fail to excite them At these high temperatures humans perceive heat pain rather than sensations of warmth The corresponding temperature for cool activation is 5C The frequency of discharge of cold or warmth fibres is linearly related to the size of

the warming or cooling step.

According to one embodiment of the present invention, the apparatus comprises the described means for induction of stimuli in the form of both an electrical current and heat

The choice of using heat as stimuli, instead of an electrical current, can be dependent on the sensation to be measured. Test results have shown that pain thresholds were elevated following intrathecal morphine when using an argon laser technique for heat stimuli induction, whereas no pain threshold changes were detected using electrical stimulation. A hypothetical explanation to the different results has been that the morphine has different effects on different nerve fibre populations, of which C-fibres are activated by heat and A-delta fibres are activated by electrical stimulation. Similar results have been found when measuring pain threshold elevation following treatment with acupuncture.

According to the invention, the apparatus can be used not only to indicate sensations, but also integrated skills, impairments and disabilities, e.g. quality of life and active daily living, ADL. When using the apparatus for such a purpose, the measured perception threshold and pain threshold are used as lower and upper values on a scale, or vice versa. The integrated skill is then indicated by selecting the appropriate stimulation level, and the measurement result is referred to said scale. The induced stimuli can be either an electrical current or heat. Furthermore, the measurement, or indication, can be performed either by the person subjected by the stimuli, or by another person, based upon this other person's realisation of the integrated skills of the subjective person.

In an exemplifying prototype used for an experimental study of an aspect of the invention, an electrical current stimulus was provided by means of an electrical current generator capable of delivering a current through a resistance of 13 kohm. The current was pulsated in a pulsating square wave shape having a fixed amplitude of 10 mA and a frequency of 10 Hz. The pulse width was increased from 0 to 500 microseconds in steps of about 8 microseconds. The increase rate of the pulse width was devised such that the pulse width was increased from 0 to 250 microseconds during 25, 30 or 35 second, never repeating the same increase rate twice in a sequence, and from 251 to 500 microseconds during 20 seconds. The results of this experimental study verifies the proper function of the invention.

A preferred procedure for using the inventive apparatus for measuring a sensation, using a stimulus signal with an increasing value, comprises the steps of:

- connecting the induction means 104 to a skin portion of the patient, preferably into a finger grip;
- commencing the stimulus induction by pushing the control switch 124, whereupon an increasing stimulus is generated;
- the patient halting the increase of the stimulus signal when sensing that the induced stimulus matches the sensation to be measured, whereby the stimulus signal is held at a constant level

- the patient considering if said constant level matches the sensation to be measured;
- if indeed considering the stimulation halted at the constant level to represent a good match, the patient releasing the grip of the induction means, the resulting open circuit ending with the released induction means thereby triggering the apparatus to store the currently generated stimulus level;
- if not considering the stimulus at the constant level to match with the sensation to be measured, the patient pushing the control switch once again, thereby continuing the increase from the halted level, until finding a level that better matches the sensation.

As previously described, the inventive apparatus can also be used for measuring a perception or an integrated skill, and may furthermore use a random variation of the stimulus signal instead of an increasing value. The described procedure is however easily modified to any of those cases, and is not intended to be limited by the specific wording of the included steps.

PCT/EP00/08207

Amendments in response to telephone communication 05/11/2001

Claims

1. A sensation level measuring device comprising a stimulator devised to deliver a physical stimulus, **characterized in**
- means for delivering said physical stimulus as a pulsating stimulus having a predetermined frequency;
- means for varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating stimulus for the purpose of comparing said physical stimulus with an affective component of said sensation.

2. The measuring device as recited in claim 1, wherein said predetermined frequency is fixed, and said pulse width is varied while maintaining a fixed amplitude.

3. The measuring device as recited in claim 1 or 2, wherein said stimulator is further devised to vary the amplitude of said pulsating physical stimulus for the purpose of comparing said physical stimulus with a sensory component of said sensation.

4. The measuring device as recited in claim 3, wherein said stimulator devised to selectively deliver a first physical stimulus having said varied pulse width or a second physical stimulus having said varied amplitude, for the purpose of separating an affective component from a sensory component of said measured sensation.

5. The measuring device as recited in claim 4, wherein the physical stimulus is achieved by means of delivering electrical energy to the skin of a human being.

6. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave in the range of 0-1000 microseconds.

7. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

8. The measuring device as recited in claim 5, wherein said electrical energy is voltage controlled.

9. The measuring device as recited in claim 5, wherein said electrical energy is current

controlled.

10. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

11. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering said electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

12. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

13. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

14. The measuring device as recited in claim 1, 2, 3 or 4 wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

15. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

16. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange or induction stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

17. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of delivering heat or radiation energy to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

18. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in

the range of 10 to 60 seconds.

19. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

20. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

21. The measuring device as recited in claim 14, comprising a resistive coil or a peltier element.

22. The measuring device as recited in claim 14, comprising a laser, such as an argon laser or a carbon dioxide laser.

23. The measuring device as recited in claim 1, 2, 3 or 4 wherein:
-said stimulator comprises a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person; and
the measuring device further comprising
-an indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-a level registration means (114,116) for registering a sensation level value corresponding to said sensation, and
- means (122) for varying the pulse width of the physical stimulus with a constant predetermined frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

24. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a sensation.

25. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a perception.

26. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of an integrated skill.

27. A method of measuring the level of a sensation, perception or integrated skill of a person, characterized in the steps of:
delivering to said person a pulse width modulated pulsating physical stimulus for comparing with an affective component of said sensation;
registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

28. The method as recited in claim 27, further comprising the step of varying the pulse width of the pulsating physical stimulus in the range of 0-1000 microseconds.

29. The method as recited in claim 27, further comprising the step of delivering a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

30. The method as recited in claim 27, further comprising the step of delivering a physical stimulus that is comparable with a sensory component of said sensation.

31. The method as recited in claim 27, further comprising the step of delivering an amplitude modulated pulsating physical stimulus.

32. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by delivering electrical energy to the skin of a human being.

33. The method as recited in claim 32, wherein said electrical energy is voltage controlled.

34. The method as recited in claim 32, wherein said electrical energy is current controlled.

35. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

36. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

37. The method as recited in claim 32, further comprising the step of delivering a electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

38. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

AMENDED SHEET

39. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

40. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

41. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

42. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by exchanging thermal energy with or inducing thermal energy into the skin of a human being.

43. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

44. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

45. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

46. The method as recited in claim 42, further comprising the step of achieving the physical stimulus by delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

47. The method as recited in claim 46, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

48. The method as recited in claim 42, further comprising the step of achieving the

physical stimulus by cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

49. The method as recited in claim 48, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

50. The method as recited in claim 27, for measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
selectively delivering to said person a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation;
registering a sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation;
indicating whether the registered sensation level value is based on said first physical stimulus or said second physical stimulus respectively.

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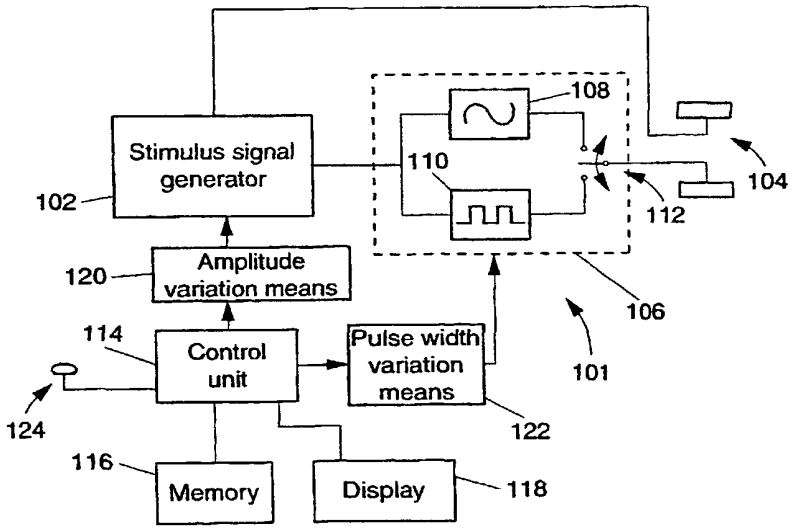

(57) Abstract: An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with stimulating means for inducing a physical stimulus to the person and means for registering a sensation level value in response to an indication signal from the person that the induced stimulus corresponds to the sensation to be measured. The apparatus is devised to provide a pulsating stimulus having means for varying the pulsating properties of the stimulus with pulse width modulation in order to measure the affective component of sensations. Further developments of the apparatus is also provided with amplitude variation means in order to measure the sensory component of sensations.

WO 01/13793 A1

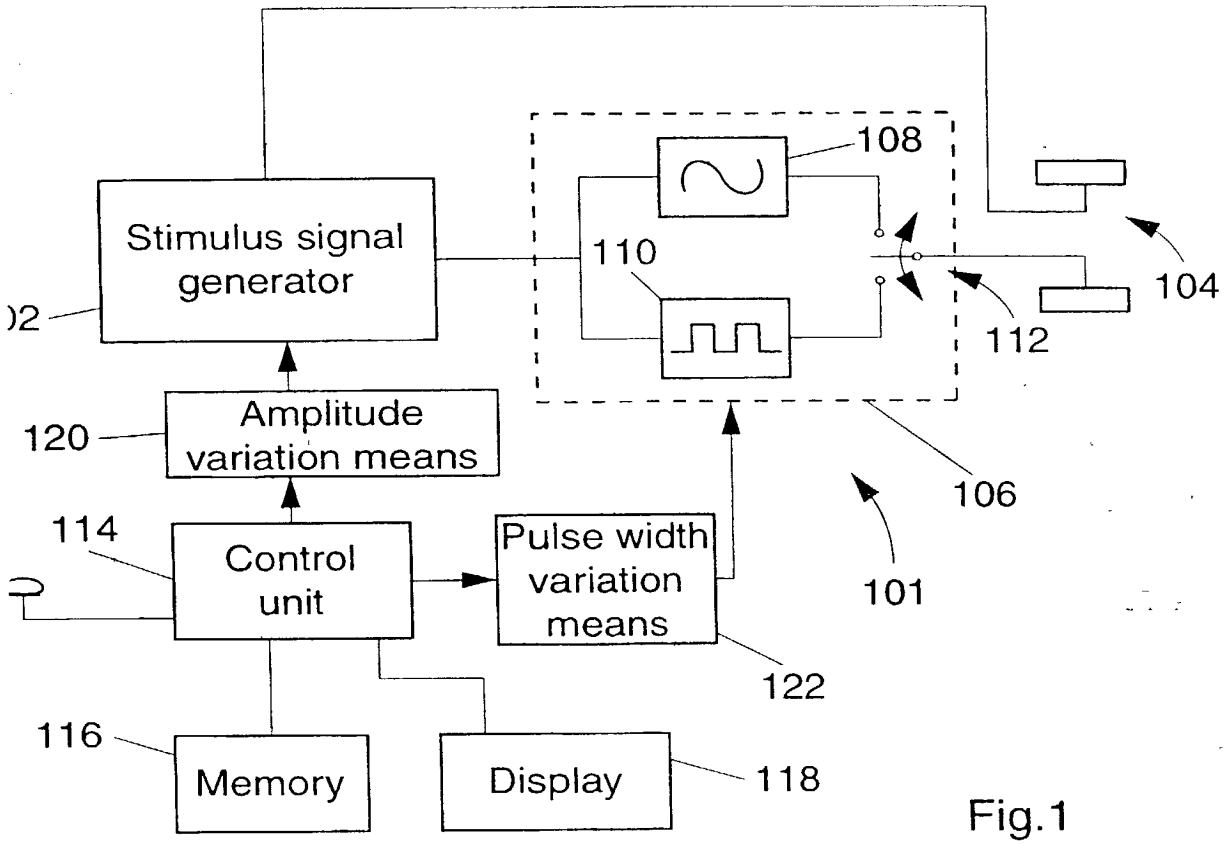

Fig.1

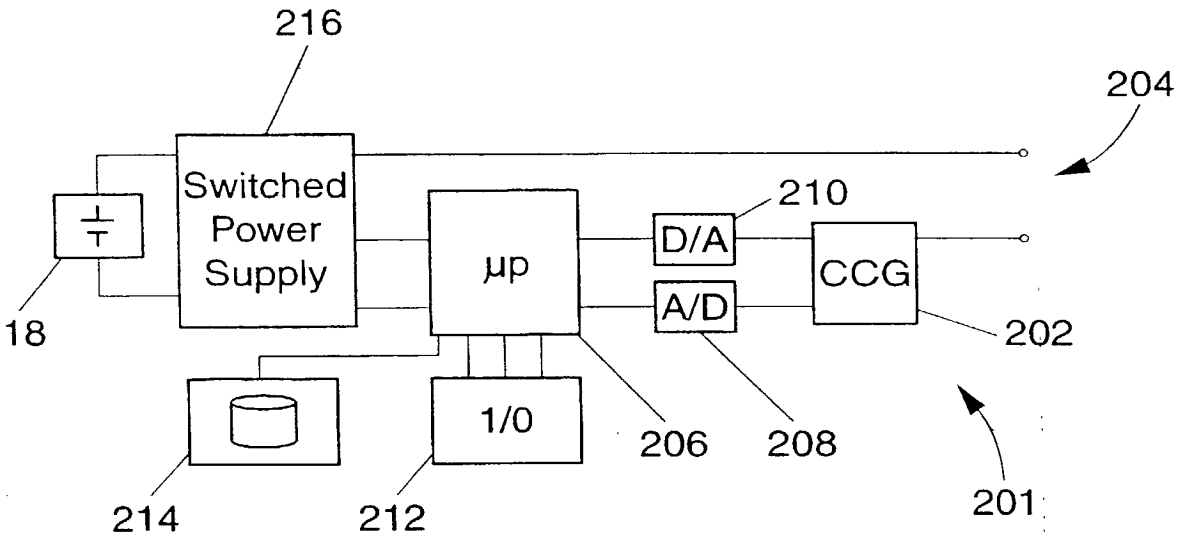

Fig.2

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY DOCKET NUMBER 1774/0K314

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for and which a patent is sought on the invention entitled:

APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

the specification of which (check only one item below):

[] is attached hereto.

[] was filed as United States application

Serial No. _____

on _____

and was amended

on _____ (if applicable).

[X] was filed as PCT international application

Number PCT/EP00/08207

on August 21, 2000

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a)

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. 119
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			[] YES [] NO
			[] YES [] NO
			[] YES [] NO

US

Combined Declaration for Patent Application and Power of Attorney (Continued) (Includes Reference to PCT International Applications)	ATTY'S DOCKET NUMBER 1774/0K314

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S APPLICATIONS		STATUS (Check one)		
U.S APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO.	PCT FILING DATE	U.S SERIAL NUMBER ASSIGNED (if any)
PCT/EP00/08207	8/21/00	10/070,072

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Morris Reisen #15,108, Gordon D. Caplein #19,165, William F. Dudine, Jr. #20,569, Michael J. Sweedler #19,937, S. Peter Ludwig #25,351, Paul Fields #20,298, Joseph B. Lerch #26,936, Melvin C. Garner #26,272, Ethan Horwitz #27,646, Beverly B. Goodwin #28,417, Adda C. Gogoris #29,714, Martin E. Goldstein #20,869, Bert J. Lewen 19,407, Henry Sternberg #22,408, Peter C. Schechter #31,862, Robert Schaffer #31,194,Robert C. Sullivan, Jr. #30,499, Joseph R. Robinson #33,446, Paul F. Fehlner #35,135, Scott G. Lindvall #40,325, Pierre R. Yanney #35,418, and John C. Todaro #36,036

22

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	
Daniel Larsson		
DATE Aug 21, 2002	DATE Aug 26, 2002	